

## REMARKS

Claims 28, 29, 36 and 50-52 are pending in the instant application. Applicants have amended claim 28 and added claims 50-52. The amendments and additions made herewith are fully supported by the as-filed specification. Thus, no new matter has been added.

## CLAIM REJECTIONS - § 112, FIRST PARAGRAPH

### Enablement

The Examiner has rejected claims 28, 29 and 36 under 35 U.S.C. § 112, first paragraph, contending that the specification is not enabling “for a method of modulating an immune response, said method comprising administering a substantially pure polypeptide consisting of the amino acid sequence of SEQ ID NO:1 to a subject in need thereof in an amount sufficient to inhibit **any** immune response by the subject against said polypeptide” (*See*, Office Action at page 2, ¶4). Applicants respectfully traverse this rejection as it applies to pending claims 28, 29 36 and 50-52.

The Examiner has acknowledged that the specification is enabling “for a method of modulating an immune response, said method comprising administering a substantially pure polypeptide consisting of the amino acid sequence of SEQ ID NO:1 to a subject in need thereof in an amount sufficient to inhibit T cell response by the subject against polypeptide” (*See*, Office Action at page 2, ¶4). The Examiner has further stated that “(t)he specification of page 3 discloses that the method includes administering an Api m6 polypeptide of SEQ ID NO:1 to a subject to inhibit an immune response such as T-cell response or to diminish allergic response of a mammal (see page 19, at line 17) upon exposure to said polypeptide.” (*See*, Office Action at page 3, lines 17-20).

Applicants have herewith amended independent claim 28, from which claims 29 and 36 properly depend, to replace the term “an immune response” with the term “a T-cell immune response.” Thus, claim 28 as amended recites a substantially pure bee venom polypeptide consisting of the amino acid sequence of SEQ ID NO:1 as well as a specific way of modulating an immune response (*i.e.*, inhibiting a T-cell immune response). Applicants have also added claims 50-52. Claim 50, from which claims 51 and 52 properly depend, is drawn to a “method

of modulating an immune response to bee venom, said method comprising administering a substantially pure polypeptide consisting of the amino acid sequence of SEQ ID NO:1 to a subject in need thereof in an amount sufficient to diminish an allergic response by the subject against said bee venom.” As stated by the Examiner (*See*, Office Action at page 3, lines 17-20), claim 28 as amended herein and claims 50-52 as added herein are enabled by the instant specification. Thus, this rejection, as it applies to pending claims 28, 29 36 and 50-52, should be withdrawn.

### **Written Description**

The Examiner has also rejected claims 28, 29 and 36 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention. Specifically, the Examiner has stated that specification does not reasonably provide a written description for a “method of modulating an immune response, said method comprising administering a substantially pure polypeptide consisting of the amino acid sequence of SEQ ID NO:1 to a subject in need thereof in an amount sufficient to inhibit **any** immune response by the subject against said polypeptide” (*See*, Office Action at page 5). Applicants respectfully traverse this rejection as it applies to claims 28, 29 36 as amended herein and new claims 50-52.

As noted, Applicant has herewith amended independent claim 28, from which claims 29 and 36 properly depend, to delete the term “an immune response” with recite the term “a T-cell immune response.” Also, Applicants have added claims 50-52. Claim 50, from which claims 51 and 52 properly depend, is drawn to a “method of modulating an immune response to bee venom, said method comprising administering a substantially pure polypeptide consisting of the amino acid sequence of SEQ ID NO:1 to a subject in need thereof in an amount sufficient to diminish an allergic response by the subject against said bee venom.” As discussed *supra*, the Examiner has stated that “(t)he specification of page 3 discloses that the method includes administering an Api m6 polypeptide of SEQ ID NO:1 to a subject to inhibit an immune response such as T-cell response or to diminish allergic response of a mammal (see page 19, at line 17) upon exposure to said polypeptide.” (*See*, Office Action at page 3, lines 17-20).

Thus, Applicants contend that independent claim 28 (and dependent claims 29 and 36), as amended herein, and claims 50-52, as added herein, contain subject matter that is sufficiently described in the specification so as to reasonably convey to those skilled in the art that Applicant was in possession of the claimed invention. Accordingly, Applicant requests that this rejection, as it applies to pending claims 28, 29 36 and 50-52, should be withdrawn

### CONCLUSION

On the basis of the foregoing amendments and remarks, Applicant respectfully submits that the pending claims are in condition for allowance. Should any questions or issues arise concerning this application, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

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